

Article 1. Definitions

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(1) Adopt new Section 1029.7 to read:

1029.7. Accredited College or University.

“Accredited college or university” means an educational facility which has met the standards of the United States of America Accrediting Commission for Senior Colleges and Universities or the Accrediting Commission for Community and Junior Colleges; or, if a non-United States college or university, one that is evaluated and found equivalent by the American Association of Collegiate Registrars and Admissions Officers.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1260, 1261, 1261.5, 1263, and 1264, Business and Professions Code.

(2) Adopt new Section 1029.31 to read:

1029.31. Clinical Consultant.

“Clinical consultant” means a person who meets the requirements of Section 493.1455 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides clinical consultation of a laboratory in accordance with Section 1036 of this title and Section 493.1457 of Title 42, Code of Federal Regulations, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(3) Adopt new Section 1029.32 to read:

1029.32. Clinical Cytogenetics.

"Clinical cytogenetics" means the techniques used to isolate, replicate and identify whole or parts of human chromosomes including culturing, manipulation, banding, staining and hybridizing, and analysis with respect to genotype and phenotype.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1207, 1210, 1261.5, and 1264, Business and Professions Code.

(4) Adopt new Section 1029.33 to read:

1029.33. Clinical Genetic Molecular Biology.

"Clinical genetic molecular biology" means the determination of all the aspects of molecular organizations of the nucleic acids of the human genome with respect to genotype and phenotype.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1207, 1210, 1261.5, and 1264 Business and Professions Code.

(5) Adopt new Section 1029.81 to read:

1029.81. Evidence of Satisfactory Performance.

"Evidence of satisfactory performance" means a copy of a document issued to an examinee by the department for satisfactory performance on a department-administered licensing written examination, or by a certifying board or organization indicating satisfactory performance by the examinee on a written certifying examination.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1208, 1260, 1261, 1261.5, 1262 and 1264, Business and Professions Code.

(6) Adopt new Section 1029.82 to read:

1029.82. Field Related to Genetics.

"Field related to genetics" means a major in molecular biology, reproductive biology, biochemistry, clinical genetics, medical genetics, clinical cytogenetics, biochemical genetics, human genetics, clinical laboratory science, or clinical molecular genetics.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Section 1206 and 1210, Business and Professions Code.

(7) Adopt new Section 1029.83 to read:

1029.83. General Supervisor.

“General supervisor” means a person who meets the requirements of Section 493.1461 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides general supervision of a laboratory in accordance with Section 1036.1 of this title and Section 493.1463 of Title 42, Code of Federal Regulations, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(8) Adopt new Section 1029.86 to read:

1029.86. High Complexity Tests or Examinations.

“High complexity tests or examinations” mean those clinical laboratory tests classified as high complexity by the federal government (Centers for Disease Control and Prevention or the Food and Drug Administration) according to the protocol stated in Title 42, Code of Federal Regulations, Part 493, Section 17, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1202.5, 1203, 1204, 1206, 1206.5, 1207, 1209.1, 1210 and 1265, Business and Professions Code.

(9) Adopt new Section 1029.111 to read:

1029.111 Licensed Healthcare Professional.

“Licensed healthcare professional” means any person acting within their scope of practice who holds a active, valid license pursuant to the Business and Professions Code, which authorizes him or her to provide services related to the health of another person.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206.5 and 1208, Business and Professions Code.

(10) Adopt new Section 1029.118 to read:

1029.118. Moderate Complexity Laboratory Technical Consultant.

“Moderate complexity laboratory technical consultant” means a person who meets the qualifications of Section 493.1411 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical oversight in accordance with Section 1036.2 of this title and Section 493.1413 of Title 42, Code of Federal Regulations, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(11) Adopt new Section 1029.119 to read:

1029.119. Moderate Complexity Tests or Examinations.

“Moderate complexity tests or examinations” mean those clinical laboratory tests classified as moderate complexity by the federal government (Centers for Disease Control and Prevention or the Food and Drug Administration) according to the protocol stated in Title 42, Code of Federal Regulations, Part 493, Section 17, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1202.5, 1203, 1204, 1206, 1206.5, 1207, 1209.1, 1210 and 1265, Business and Professions Code.

(12) Adopt new Section 1029.126 to read:

1029.126. Oral and Maxillofacial Pathologist Laboratory Director.

“Oral and maxillofacial pathologist laboratory director” means a dentist who possesses a valid, unexpired license to direct an oral pathology laboratory in all areas of anatomic and clinical pathology related to the oral and maxillofacial region.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1207, 1208, and 1209, Business and Professions Code.

(13) Adopt new Section 1029.127 to read:

1029.127 Oral Pathology.

“Oral pathology” means the subspecialty of pathology that deals with the nature, identification and management of diseases affecting the oral and maxillofacial regions, which investigates the causes, processes and effects of these diseases, and includes research and diagnosis of diseases using clinical, radiographic, microscopic, biochemical or other examinations.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Section 1206, and 1207 Business and Professions Code.

(14) Adopt new Section 1029.153 to read:

1029.153. Satisfactory Performance.

"Satisfactory performance" means achieving at least the minimum grade that an examinee must obtain to get a passing score on a written or oral examination.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1208, 1260, 1261, 1261.5, 1262 and 1264, Business and Professions Code.

(15) Adopt new Section 1029.169 to read:

1029.169. Subspecialty of Histocompatibility.

“Subspecialty of histocompatibility” means those activities, including renal allotransplantation, non-renal transplantation, and HLA typing, that are performed in a histocompatibility laboratory as specified in Section 493.1265 of Title 42, Code of Federal Regulations, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1209.1 and 1210, Business and Professions Code.

(16) Adopt new Section 1029.171 to read:

1029.171. Technical Supervisor.

“Technical supervisor” means a person who meets the qualifications of Section 493.1449 of Title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical supervision in accordance with Section 1036.4 of this title and Section 493.1451 of Title 42, Code of Federal Regulations, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1203, 1204, 1207, 1209, 1209.1 and 1210, Business and Professions Code.

(17) Adopt new Section 1029.196 to read:

1029.196. Waived Laboratory Technical Consultant.

“Waived laboratory technical consultant” means a person who meets the qualifications specified in Section 1036.3 (a) and provides technical oversight of a waived laboratory as specified in Section 1036.3 (b) and (c).

NOTE: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1203, 1204, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code.

(18) Adopt new Section 1029.197 to read:

1029.197. Waived Tests.

“Waived tests” mean those clinical laboratory tests classified as waived by the federal government (Centers for Disease Control and Prevention or the Food and Drug Administration) according to protocol stated in Title 42, Code of Federal Regulations, Part 493, Section 15, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1202.5, 1203, 1204, 1206, 1206.5, 1207, 1209.1, 1210 and 1265, Business and Professions Code.

Article 1.5. Licensure of Clinical Laboratory Personnel

(19) Amend Section 1030.5 to read:

1030.5. Licensure of Clinical Chemists, Clinical Microbiologists, Clinical Toxicologists, Clinical Genetic Molecular Biologists and Clinical Cytogeneticists -

A written and oral-examination shall be given to each applicant for licensure as a clinical chemist, clinical microbiologist, clinical toxicologist, clinical genetic molecular biologist or clinical cytogeneticist. In addition to the requirements for licensure as specified in Section 1264 of the Business and Professions Code, an applicant shall have completed one year of training as a licensed trainee or equivalent in his specialty or subspecialty pursuant to Section 1207 of the Business and Professions Code. Also, each applicant shall have completed three years of experience in his or her specialty pursuant to Section 1210 of the Business and Professions Code in a licensed clinical laboratory two years of which shall have been at a supervisory level.

NOTE: Authority cited: Sections 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1204, 1205, 1207, 1210, 1264 and 1265, Business and Professions Code.

(20) Adopt a new Section 1030.6 to read:

1030.6. Licensure of Clinical Cytogenetists.

(a) Except for a clinical laboratory bioanalyst licensed by the department who meets the laboratory director qualifications for high complexity testing in Section 1443 of Title 42, Code of Federal Regulations, Part 493, as published October, 1994, or a pathologist who meets the laboratory director qualifications in Section 1443 (b)(1) of Title 42, Code of Federal Regulation, Part 493, as published October 1, 1994, a laboratory director of a clinical laboratory that performs tests or examinations in the subspecialty of clinical cytogenetics within the specialty of genetics shall possess a valid clinical cytogeneticist license issued by the department.

(b) In order to be eligible for licensure as a clinical cytogeneticist, an applicant shall:

(1) Be a physician and surgeon licensed by the State to practice medicine pursuant to Chapter 5 of the Business and Professions Code, and have:

(A) Two years training in clinical cytogenetics in a training program approved by the American Board of Medical Genetics (ABMG) or the Canadian Council of Medical Genetics (CCMG), and approved by the department pursuant to Section 1286, Business and Professions Code, Chapter 3, and

(B) Two years experience directing or supervising high complexity genetics testing in a clinical laboratory; and

(C) Evidence of satisfactory performance on a written examination in clinical cytogenetics administered by the ABMG, CCMG or the department; and

(D) Demonstrated satisfactory performance on an oral examination regarding Business and Professions Code, Chapter 3 and Title 42, CFR, Section 493, as published October 1, 1994; or

(2) Hold an earned doctoral degree in a biological science or field related to genetics from an accredited university with thirty semester or equivalent quarter hours of post-baccalaureate course credit in genetics posted on an official transcript from the university registrar; and

(A) Have two years training in clinical cytogenetics in a training program approved by the ABMG, or the CCMG and approved by the department pursuant to Section 1286, Chapter 3, of Business and Professions Code; and

(B) Have two years experience supervising or performing clinical laboratory tests or examinations in clinical cytogenetics in a clinical laboratory; and

(C) Provide evidence of satisfactory performance on a written examination in clinical cytogenetics administered by the ABMG, CCMG or the department; and

(D) Have demonstrated satisfactory performance on the oral examination administered by the Department regarding Business and Professions Code, Chapter 3 and Title 42 Code of Federal Regulation, Section 493, as published October 1, 1994; or

(3) Have served as a laboratory director of a clinical laboratory performing laboratory tests limited to the subspecialty of cytogenetics on or before December 31, 1997 and either;

(A) Meet the laboratory director qualifications of Sections 1443 (b)(2) or 1443 (b)(3) of Title 42, Code of Federal Regulations, Part 493, as published October 1, 1994; or

(B) Hold an earned doctoral degree, have four years clinical cytogenetics training or experience in a clinical laboratory certified by HCFA in clinical cytogenetics, and provide, evidence of satisfactory performance on a written certifying examination in cytogenetics administered by the ABMG or the CCMG.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1207, 1209, 1264, 1265 and 1282, Business and Professions Code.

(21) Adopt new Section 1030.7 to read:

1030.7. Licensure of Clinical Genetic Molecular Biologists.

(a) Except for a clinical laboratory bioanalyst licensed by the department pursuant to Business and Professions Code, Chapter 3, who meets the laboratory director qualifications for high complexity testing in Section 1443 of Title 42, Code of Federal Regulations, Part 493, as published October, 1994, and a pathologist who meets the laboratory director qualifications in Section 1443 of Title 42, Code of Federal Regulations, Part 493, as published October 1, 1994, a laboratory director of a clinical laboratory that performs tests or examinations in the subspecialty of molecular biology related to the diagnosis of abnormalities related to human genetic disorders shall possess a valid clinical genetic molecular biologist license issued by the department.

(b) In order to be eligible for licensure as a clinical genetic molecular biologist, an applicant shall:

(1) Be a physician and surgeon licensed by the State pursuant to Chapter 5 of Business and Professions Code, to practice medicine and have:

(A) Two years of training in clinical genetic molecular biology in a training program approved by the American Board of Medical Genetics (ABMG) or the Canadian Council of Medical Genetics (CCMG), and approved by the department pursuant to Section 1286, Chapter 3 of Business and Professions Code; and

(B) Two years experience directing or supervising high complexity genetics testing in a licensed clinical laboratory; and

(C) Evidence of satisfactory performance on a written examination in genetic molecular biology administered by the ABMG or CCMG or the department; and

(D) Demonstrated satisfactory performance on an oral examination administered by the department regarding Chapter 3 of Business and Professions Code and Section 493 of Title 42 Code of Federal Regulations as published October 1, 1994; or

(2) Hold an earned doctoral degree in a biological science or field related to genetics from an accredited university with 30 semester or equivalent quarter hours of post-baccalaureate course credit in genetics posted on an official transcript from the university registrar; and

(A) Have two years training in clinical genetic molecular biology in a training program approved by the ABMG or the CCMG, and approved by the department pursuant to Section 1286, Chapter 3 of Business and Professions Code; and

(B) Have two years experience supervising or performing clinical laboratory tests or examinations in clinical genetic molecular biology in a clinical laboratory; and

(C) Provide evidence of satisfactory performance on a written certifying examination in genetic molecular biology administered by the ABMG or CCMG or the department; and

(D) Have demonstrated satisfactory performance in the oral examination regarding Chapter 3 of Business and Professions Code and Section 493 of Title 42 Code of Federal Regulations as published October 1, 1994; or

(3) Have served as a laboratory director of a clinical laboratory performing laboratory tests limited to the subspecialty of molecular biology related to the diagnosis of human genetic abnormalities on or before December 31, 1997, and either:

(A) Meet the qualifications of Sections 1443 (a), 1443 (b)(2), or 1443 (b)(3) of Title 42, Code of Federal Regulations, Part 493, as published October 1, 1994; or

(B) Hold an earned doctoral degree, have four years clinical genetic molecular biology training or experience in a licensed clinical laboratory certified by HCFA in molecular diagnostic testing, and provide evidence of satisfactory performance on a written certifying examination in genetic molecular biology administered by the ABMG or CCMG.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1207, 1209, 1264, 1265 and 1282, Business and Professions Code.

(22) Adopt new Section 1030.8 to read:

1030.8. Licensure of Oral Pathologists.

(a) Except for a pathologist who meets the laboratory director qualifications of Section 1443(b)(1) of Title 42, Code of Federal Regulations, Part 493, as published October 1, 1994, a laboratory director of an oral pathology laboratory shall possess a valid oral pathologist laboratory director license issued by the department.

(b) In order to be eligible for licensure as an oral pathologist laboratory director, an applicant shall:

(1) Be a doctor of dental surgery licensed by the State pursuant to Chapter 4 of Business and Professions Code to practice dentistry and have:

(A) One year of advanced training in oral and maxillofacial pathology in a training program approved by the American Dental Association (ADA) Committee on Accreditation of Dental and Dental Auxiliary Education Programs in an educational institution; and

(B) An additional four years full time experience in oral pathology, and

(C) Evidence of satisfactory performance on the oral pathologist certification examination administered by the American Board of Oral Pathology (ABOP); and

(D) Demonstrated satisfactory performance on an oral examination administered by the department regarding Chapter 3 of Business and Professions Code and Title 42, Code of Federal Regulations, Part 493 as published October 1, 1994; or

(2) Have served as a laboratory director of a oral pathology laboratory on or before January 1, 1996, and be a doctor of dental surgery licensed by the State pursuant to Chapter 4 of Business and Professions Code to practice dentistry, and provide evidence

of satisfactory performance on a certifying examination in oral pathology and maxillofacial administered by the ABOP.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1207, 1208, 1209 and 1264, Business and Profession Code.

(23) Amend Section 1031 to read:

1031. Licensure of Clinical Laboratory Specialists.

(a) The minimum requirements for admission to the limited scientist examination shall be as follows:

(1) An applicant for admission to the examination for a clinical chemist scientist license shall meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in chemistry or equivalent major which shall include at least 25 semester or 38 quarter units in chemistry including courses in analytical chemistry and instrumentation. This coursework shall be verified by an official transcript showing college or university courses, training and degree posted by an accredited college or university; and

(B) Have completed one year post-baccalaureate training or experience in all areas of the specialty of chemistry, as listed in (b)(1) below, in a licensed clinical laboratory.

(2) An applicant for admission to the examination for a clinical microbiologist scientist shall meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in microbiology or an equivalent major which shall include at least 25 semester or 38 quarter units in biology including courses in medical or pathogenic microbiology or bacteriology. This coursework shall be verified by an official transcript showing college or university courses, training and degree posted by an accredited college or university ; and

(B) Have completed one year post-baccalaureate training or experience in all areas of the specialty of microbiology, as listed in (b)(2) below, in a licensed clinical laboratory.

(3) An applicant for admission to the examination for a clinical immunohematologist scientist license shall meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in biology, clinical laboratory science or equivalent major which shall include at least 25 semester or 38 quarter units in biology. This coursework shall be verified by an official transcript showing college or university courses, training and degree posted by an accredited college or university ; and

(B) Have completed one year post-baccalaureate training or experience in all areas of the specialty of immunohematology, as listed in (b)(3) below, in a licensed clinical laboratory.

(4) An applicant for admission to the examination for clinical toxicologist scientist license shall meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in chemistry or equivalent major which shall include at least 25 semester or 38 quarter units in chemistry including analytical chemistry or quantitative analysis. This coursework shall be verified by an official transcript showing college or university courses, training and degree posted by a college or university from an accredited college or university; and

(B) Have completed one year post-baccalaureate training or experience in the specialty of toxicology, as specified in (b)(4) below, in a licensed clinical laboratory.

(5) An applicant for admission to the examination for a clinical hematologist scientist license shall meet both of the following requirements:

(A) Hold a baccalaureate degree in biology, clinical laboratory science or an equivalent major which shall include at least 25 semester or 38 quarter units in biology.

This coursework shall be verified by an official transcript showing college or university courses, training and degree posted by an accredited college or university; and

(B) Have one year of post-baccalaureate training or experience in all areas of the specialty of hematology, as specified in (b)(5) below, in a licensed clinical laboratory.

(b) Any license issued under this section shall specify the particular specialty or subspecialty in which the licensee may perform tests under such license. A person licensed as:

(1) A clinical chemist scientist shall perform clinical laboratory tests or examinations classified as high complexity under CLIA in the specialties of chemistry, including routine chemistry, clinical microscopy, endocrinology and toxicology; immunology, including diagnostic immunology and syphilis serology; and molecular biology.

(2) A clinical microbiologist scientist shall perform clinical laboratory tests or examinations classified as high complexity under CLIA in the specialties of microbiology including bacteriology, mycobacteriology, mycology, parasitology, and virology; immunology, including diagnostic immunology and syphilis serology; and molecular biology.

(3) A clinical immunohematologist scientist shall perform clinical laboratory tests or examinations classified as high complexity under CLIA limited to the specialty of immunohematology including ABO/Rh blood grouping and typing, unexpected antibody detection, compatibility testing and antibody identification.

(4) A clinical toxicologist scientist shall perform clinical laboratory tests or examinations classified as high complexity under CLIA limited to the specialty of toxicology.

(5) A clinical hematologist scientist shall perform clinical laboratory tests or examinations classified as high complexity under CLIA limited to the specialty of hematology including routine hematology and coagulation.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1209, 1209.1, 1210 and 1261, Business and Professions Code.

(24) Adopt new Section 1031.1 to read:

1031.1. Licensure of Clinical Histocompatibility Scientists.

(a) Each person performing high complexity laboratory tests or examinations in the subspecialty of histocompatibility in a licensed clinical laboratory shall possess a valid clinical histocompatibility scientist license except for the following persons:

(1) A physician and surgeon licensed by the State to practice medicine pursuant to chapter 5 of Business and Professions Code; or

(2) A histocompatibility laboratory director licensed pursuant to chapter 3 of Business and Professions Code; or

(3) A clinical laboratory bioanalyst licensed pursuant to chapter 3 of Business and Professions Code; or

(4) A clinical laboratory scientist licensed pursuant to chapter 3 of Business and Professions Code.

(b) In order to be eligible for licensure as a clinical histocompatibility scientist an applicant shall:

(1) Hold a baccalaureate or higher degree in a biological or clinical laboratory science from an accredited college or university; and

(2) Have one year of clinical laboratory experience in all areas of clinical histocompatibility testing in a clinical laboratory; and

(3) Provide evidence of satisfactory performance on a written examination in histocompatibility administered by the American Board of Histocompatibility and Immunogenetics or the department.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1209, 1209.1, 1210 and 1261, Business and Professions Code.

(25) Adopt a new Section 1031.4 to read:

1031.4. Requirements and Timeframes for Applications for Licensure.

(a) An application for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations under chapter 3 of Business and Professions Code shall be considered complete when the following is provided to the department:

(1) Name and address, including city, state and zip code; and

(2) Social security number of the applicant (optional); and

(3) Gender and birthdate; and

(4) License for which the applicant is applying; and

(5) Whether the applicant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations; and

(6) Documentation of the applicant's education including:

(A) Name, address, major course of study, dates of attendance, number of credits, and degree/completion date for colleges and universities attended by the applicant; and

(B) Official transcripts from the registrar of accredited colleges or universities attended by the applicant showing all courses, course credits, degrees conferred and date of conference; and

(C) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved for legal documents.

(7) Documentation of the applicant's training including:

(A) Name, address, dates of training, specialty and subspecialty areas of training, length of time in each specialty and subspecialty area of training; and

(B) Signed documentation from the training program director that this training had been successfully completed; and

(8) Documentation of the applicant's experience, appropriate to the specific license for which the applicant is applying, including the following:

(A) Facility name, address, dates of employment, number of hours per week employed, the specialties and subspecialties in which clinical laboratory tests or examinations were performed and a description of laboratory tests, procedures and examinations performed; and

(B) Signed documentation of such experience from the director of the laboratory; and

(9) Evidence of satisfactory performance on a licensing examination pursuant to Section 1029.81; and

(10) Signature of the applicant, telephone number and date of application; and

(11) Payment of license application fee pursuant to Business and Professions Code Section 1300.

(b) Applications for admission to a state-administered licensing examination shall be complete when the information specified in Section 1034.1 (a) has been received by the department. For an applicant to be eligible for a scheduled examination, the completed application must be received at least 120 days prior to the examination date as published by the Department of Health Services, as verified by postmark date of the completed application. When applying for admission to the examination, the applicant

shall state whether he or she has previously applied to the department for admission to an examination.

(c) Timeframes for processing applications for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations pursuant to chapter 3 of the Business and Professions Code shall be as follows:

(1) The department shall notify the applicant in writing within 90 days of submission of an application, one of the following:

(A) The application is complete and will be processed by the department; or

(B) The application is incomplete and not accepted for processing. The department's written notification shall include the specific information, documentation or fee in which the application is deficient; or

(C) The application has been reviewed and does not meet the requirements and that approval is denied. The department shall give written notification of the basis for the denial.

(2) The department shall notify the applicant within 90 days of postmark date of resubmission of application requirements pursuant to (c)(1)(B) whether the application has been approved or denied.

(3) Written notification by the department to applicants shall be deemed to occur on the date of the postmark from the department.

(4) The department shall deem an application abandoned by an applicant who fails to respond or to supply all information, documents, verification or fee within 30 days of notification by the department.

(5) The department's time periods for processing an application for licensure from the date the application is complete to the date the final decision is made regarding an approval are as follows:

(A) The median time for processing an application is 90 days;

(B) The minimum time for processing an application is 30 days; and

(C) The maximum time for processing an application is 150 days.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1241, 1260, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301, 1301.1, and 1320 Business and Professions Code.

(26) Adopt a new Section 1031.5 to read:

1031.5 Requirements and Timeframes for Renewal of Licenses

(a) To remain active, licenses shall be renewed by filing a renewal application 60 days prior to the end of the license period.

(b) A complete license renewal application shall include name and address of the licensee, license number, current work location, documentation of continuing education credits, an attestation that the licensee has not been convicted of any felonies or misdemeanors other than minor traffic violations in the previous year, license renewal fee, signature and date of application for renewal.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code;

Reference: Sections 1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1226, 1241, 1260, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301 and 1301.1, Business and Professions Code.

Article 2.3. Clinical Laboratory Supervisors

(27) Adopt new Section 1036 to read:

Section 1036. Clinical Consultant.

(a) Every clinical laboratory director under whom moderate or high complexity tests or examinations are performed shall employ a clinical consultant who can provide consultation about the appropriateness of testing ordered and interpretation of test results, as specified in Section 1209, chapter 3 of Business and Professions Code.

(b) The clinical consultant shall possess a current, valid license issued by the State to direct a clinical laboratory pursuant to chapter 3, Business and Professions Code, or to practice medicine or podiatry pursuant to chapter 5, Business and Professions Code appropriate to the specialties and subspecialties for which he or she is consulting.

(c) The clinical consultant shall:

(1) Provide clinical consultation to the clients of the laboratory; and

(2) Assist in their ordering tests appropriate to meet clinical expectations; and

(3) Ensure that test results include pertinent information required for interpretation;
and

(4) Communicate matters about quality of test results reported and interpretation in relation to specific patient conditions.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health Safety Code.

Reference: Sections 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code.

(28) Adopt new Section 1036.1 to read:

Section 1036.1. General Supervisor.

(a) Every clinical laboratory director under whom high complexity tests or examinations are performed shall employ a general supervisor who shall be responsible for day-to-day supervision of laboratory operation and personnel performing and reporting high complexity tests, pursuant to Section 1209, chapter 3 of Business and Professions Code.

(b) A general supervisor shall:

(1) Possess an active, valid license issued by the State to perform high complexity testing pursuant to chapter 3 of Business and Professions Code or to practice medicine, osteopathy or podiatry pursuant to chapter 5 of Business and Professions Code appropriate to the specialty or specialties they are supervising; and

(2) Have a minimum of two years experience in high complexity testing in the specialty or specialties they are supervising.

(c) The general supervisor shall be accessible to testing personnel at all times testing is performed by providing on-site, telephone or electronic consultation to resolve technical problems.

(d) The general supervisor shall be responsible for ensuring that tests and examinations are performed in compliance with chapter 3 of the Business and Professions Code and Title 42, Code of Federal Regulations, Part 493 standards as published October 1, 1994, regarding clinical laboratories.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275 Health Safety Code.

Reference: Sections 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code.

(29) Adopt new Section 1036.2 to read:

Section 1036.2. Moderate Complexity Laboratory Technical Consultant.

(a) Every laboratory director, under whom moderate complexity tests or examinations are performed, shall employ a technical consultant who is responsible for providing technical and scientific consultation for each of the specialties and subspecialties of service performed.

(b) A technical consultant of a laboratory performing moderate complexity testing shall:

(1) Possess a active, valid license issued by the State pursuant to chapter 3 of Business and Professions Code to perform high complexity testing, or to practice medicine, osteopathy or podiatry pursuant to chapter 5 of Business and Professions Code appropriate to the specialty or specialties for which he or she is consulting; and

(2) Have a minimum of two years experience in high complexity testing in the specialty or specialties he or she is consulting.

(c) The technical consultant shall be responsible for the technical and scientific oversight of the laboratory as specified in Section 1413, Title 42, Code of Federal Regulations, Part 493, as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275 Health Safety Code.

Reference: Sections 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code.

(30) Adopt new Section 1036.3 to read:

Section 1036.3. Waived Laboratory Technical Consultant.

(a) A laboratory director under whom waived tests or examinations are performed shall be responsible for technical and scientific oversight of the laboratory. Any technical consultant employed by the laboratory director to provide technical and scientific consultation to the laboratory shall:

(1) Be qualified to serve as testing personnel under Section 1206.5 (a) of Business and Professions Code; and

(2) Possess at least a baccalaureate degree from an accredited college or university; and

(3) Be a licensed health care professional, as defined in Section 1029.111; and

(4) Have at least one year of training or experience in clinical laboratory testing in those tests or examinations that he or she will be supervising; and

(5) Document competency in those tests he or she will be supervising to the laboratory director at least semiannually during the first year and annually, or whenever new instrumentation is added, thereafter.

(b) The waived laboratory technical consultant shall be accessible to the laboratory testing personnel to provide onsite, telephone or electronic consultation.

(c) The waived laboratory technical consultant shall be responsible for:

(1) Selecting, in consultation with the laboratory director, the test methodology appropriate for clinical use of test results; and

(2) Establishing a quality control program appropriate for testing performed, following test manufacturer's parameters for acceptable levels of analytical performance and

ensuring that these levels are maintained throughout the entire testing process from initial receipt to specimen, through sample analysis and test result reporting; and

(3) Resolving technical problems and ensuring remedial actions are taken and documented whenever test systems deviate from the manufacturer's established performance specifications; and

(4) Ensuring patient test results are not reported until all corrective actions have been taken and the test system is performing properly; and

(5) Identifying training needs and assuring that each individual performing tests received regular in-service training and education appropriate for waived testing; and

(6) Evaluating and documenting that the staff maintain their competency to perform test procedures and report tests promptly, accurately and proficiently by:

(A) Directly observing routine test performance, including patient preparations (if applicable), specimen handling, processing and testing; and

(B) Monitoring the recording and reporting of test results; and

(C) Reviewing quality control records and preventive maintenance records; and

(D) Directly observing performance of instrument maintenance and function checks; and

(E) Assessing problem solving skills; and

(F) Evaluating and documenting the performance of individuals responsible for waived testing at least semiannually during the first year the individual tests patient specimens. Thereafter evaluations shall be performed at least annually unless test methodology or instrumentation changes (in which case and prior to reporting patient

test results, the individual's performance shall be re-evaluated to include the use of the new test methodology or test instrumentation).

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health Safety Code.

Reference: Sections 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code.

(31) Adopt new Section 1036.4 to read:

Section 1036.4. Technical Supervisor.

(a) Every laboratory director under whom high complexity tests or examinations are performed shall employ a technical supervisor who is responsible for the technical and scientific oversight of the laboratory.

(b) A technical supervisor of laboratory performing high complexity testing shall:

(1) Possess an active, valid, license issued by the state to perform high complexity testing pursuant to chapter 3 of Business and Professions Code or to practice medicine, osteopathy or podiatry, pursuant to chapter 5 of Business and Professions Code appropriate to the specialty or specialties for which they are consulting; and

(2) Meet the experience requirements in, Section 1449 of Title 42 of the Code of Federal Regulations, Part 493, as published October 1, 1994.

(c) While not required to be on site at all times testing is performed, the technical supervisor shall be available to laboratory testing personnel at all times to provide either on-site, telephone or electronic consultation.

(d) The technical supervisor shall be responsible for all the activities listed in Section 1451 of Title 42 of the Code of Federal Regulations, Part 493 as published October 1, 1994.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health Safety Code.

Reference: Sections 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code.